DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
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March 27, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Robert W. Christensen
President
TMJ Implants, Inc.
17301 West Colfax Avenue
Suite 135
Golden, Colorado 80401

Ref. #: DEN-02-11

Dear Dr. Christensen:

On January 15 through February 22, 2002, Investigator Nicholas R. Nance of our office conducted an inspection of your establishment. Our investigator determined that your firm manufactures fossa eminence prostheses, condyle prostheses and related items for temporomandibular joint (TMJ) implantation. These are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820. The deviations are as follows:

1. Failure to establish and maintain adequate procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100(a), including:

   a. Failure to analyze processes, quality audit reports, quality records, complaints, returned product, and other quality data sources to identify existing and potential causes of nonconforming product, or other quality problems, and where necessary, to employ appropriate statistical methodology to detect recurring quality problems, as required by 21 CFR 820.100(a)(1). For example:

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i. Non-conformances during processing are not always evaluated, investigated, tracked or trended as required by your procedures.

ii. The statistical analysis does not capture all sources of quality data. There is no evidence of statistical analysis/trending of 2001/2002 quality data reflected in complaints.

iii. An appropriate statistical methodology has not been identified to be used to detect and analyze all sources of quality data, as required by procedures.

b. Failure to investigate the cause of nonconformities relating to product, processes, and the quality system, as required by 21 CFR 820.100(a)(2). For example:

Scrap logs do not document failure investigations or justification for not performing failure investigation on defective/non-conforming product.

c. Failure to implement and record changes in methods and procedures needed to correct and prevent identified quality problems, and identify the actions needed to correct and prevent recurrence of these problems, as required by 21 CFR 820.100(a)(3) & (5). For example:

Your CAPA procedure does not provide specific guidelines/timeframes in which corrective actions (CA) are to be closed. Several CA's were found to be open without evidence of risk assessment or a scheduled completion date, required by your procedures.

2. Failure to validate a process with a high degree of assurance and have that process approved and documented according to established procedures, as required by 21 CFR 820.75(a). For example:

You have not yet validated the XXXX software used to file and track complaints despite prior promises to do so.

3. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints to ensure that complaints are timely and uniformly processed, and evaluated to determine whether they represent events which are required to be reported under the Medical Device Reporting regulations, as required by 21 CFR 820.198(a). For example:

You failed to document the need for failure/complaint investigations and decisions regarding MDR applicability.

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4. Failure to maintain adequate production and process controls, as required by 21 CFR 820.70. Specifically:

   a. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications, as required by 21 CFR 820.70(a). For example:

      i. Review of Device History Records (DHRs) for product released to finished goods found that the disposition of non-conforming product is not always documented, as required by your procedures.

      ii. Non-Conforming Material Report (NCMR) forms do not always indicate or reflect non-conformities found in the DHRs and/or scrap logs.

   b. Failure to establish and maintain procedures to adequately control environmental conditions which could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR 820.70(c). For example:

      Independent environmental sampling/testing required to be performed every three months was not conducted within established timeframes.

   c. Failure to establish written procedures for the adjustment, cleaning and other maintenance of equipment to ensure that manufacturing specifications are met, as required by 21 CFR 820.70(g)(1). For example:

      i. There are no formal maintenance procedures or requirements established for the patient-specific anatomical model manufacturing equipment XXX and related equipment). Although maintenance has been performed on this equipment, records did not document what the maintenance included.

      ii. There was no documented justification for the unscheduled maintenance of the deionized water system performed on January 11, 2002. Also, there was no evidence that product manufactured prior to the performance of this maintenance was evaluated for any adverse impact which may have occurred.

5. Failure to establish and maintain a Design History File (DHF) that contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of 21 CFR 820.30, as required by 21 CFR 820.30(j). For example:

   a. The DHF for patient-specific resin anatomical models has not been approved.

   b. Design outputs, design review, risk analysis, design verification, design validation, and design transfer were dated after the release of several models.

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The above identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your establishment is in compliance with all requirements of the Federal regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the QS/GMP deficiencies are reasonably related will be cleared until the violations are corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by us without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of any other additional steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Regina A. Barrell, Compliance Officer, Food and Drug Administration, Denver District, P. O. Box 25087, Denver, CO 80225-0087. If you have any further questions, please feel free to contact Ms. Barrell at (303) 236-3043.

Sincerely,

Gerald J. Berg
Acting District Director

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